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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 91614

| EXAMINER | |
|---|---|
| ANGELL, JON E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | 10 |

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/786,043 | KOLA ET AL. | |
| | Examiner | Art Unit | |
| | J. Eric Angell | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *101-159* is/are pending in the application.

4a) Of the above claim(s) *101-108 and 114-158* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *109-113* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The amendments filed 2/27/01 (Paper No. 5), 4/16/01 (Paper No. 6) and 7/30/02 (Paper No. 7) have been entered. Claims 1-100 have been canceled.

Claims 101-158 are pending in the application.

### *Claim Objections*

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Here, claims 1-50 were cancelled and new claims 51-100 were added in the amendment filed February 2001. However, claims 1-58 were pending at that time. Therefore claims 1-50 were cancelled and the new claims were renumbered as claims 59-108, under 37 CFR 1.126. The amendment filed July 30, 2002 amending claims 102-113 and 123-131 were entered as amendments to the renumbered claims 110-121 and 123-131. It is noted that the restriction was based on the improperly numbered claims. Therefore the Groups of claims are restated below, with the correct claim numbering.

### *Election/Restrictions*

2. Restriction is required under 35 U.S.C. 121 and 372. Below is the restriction as set forth in the previous Office Action, with the correctly numbered claims.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 109-113, drawn to an isolated nucleic acid molecule comprising SEQ ID No. 1, which encodes an amino acid sequence set forth in SEQ ID No. 2.

II. Claims 114-117, drawn to an isolated nucleic acid molecule comprising SEQ ID No. 3, which encodes an amino acid sequence set forth in SEQ ID No. 4.

III. Claims 118-121, drawn to an isolated nucleic acid molecule comprising SEQ ID No. 5 or SEQ ID No. 6, which encodes an amino acid sequence set forth in SEQ ID No. 2, which encodes an amino acid sequence set forth in SEQ ID No. 7.

V. Claims 120-125, drawn to an isolated protein comprising SEQ ID No. 2, encoded by SEQ ID No. 1.

VI. Claims 126-128, drawn to an isolated protein comprising SEQ ID No. 4, encoded by SEQ ID No. 3.

VII. Claims 129-133, drawn to an isolated protein comprising SEQ ID No. 7, encoded by SEQ ID No. 5 or SEQ ID No. 6.

VIII. Claim 134-137, 139-145 and 147-149, drawn to a method for modulating ELF5 expression and a method for treatment/prophylaxis by modulating ELF5 expression wherein the methods comprise the administration of protein.

IX. Claims 134-136, 138-144 and 146-149 drawn to a method for modulating ELF5 expression and a method for treatment/prophylaxis by modulating ELF5 expression wherein the methods comprise the administration of nucleic.

X. Claim 150, drawn to a pharmaceutical composition comprising ELF5, or an agent capable of modulating ELF5 expression/activity.

XI. Claims 101-104, 151, 153, 154, drawn to an antibody directed to protein.

XII. Claims 152, 153, 154, drawn to an antibody directed to nucleic acid.

XIII. Claim 105 and 155, drawn to a method for diagnosing or monitoring a disease.

XIV. Claim 106 and 156, drawn to a method for detecting an agent capable of modulating the function of ELF5 wherein the method comprises monitoring expression.

XV. Claim 107 and 157, drawn to a method for detecting an agent capable of modulating the function of ELF5 wherein the method comprises monitoring the rate of proliferation.

XVI. Claim 108 and 158, drawn to a method for identifying an agent that binds to ELF5.

3. Applicant's election with traverse of Group I (claims 109-113) in Paper No. 9, filed July 30, 2002 is acknowledged. The traversal is on the ground(s) that the Examiner does not provide an adequate justification for restriction. This is not found persuasive because although the claims are linked by a technical feature, namely a derivative or homologue of ELF5, the claims are not linked by a special technical feature. In order for a technical feature to be a special technical feature it must be novel (see PCT rules 13.1 and 13.2). There is no special technical

feature linking the claims because derivatives of ELF5 were known in the prior art, as set forth in the art rejection below. Therefore, the restriction of the claims is proper and no groups are rejoined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 101-108 and 114-158 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9 filed July 30, 2002. Claims 109-113 are examined herein.

In the interest of compact prosecution, for the purposes of examination only, claim 112 will be treated as if it depends from claim 111 and claim 113 will be treated as if it depends from claim 110. However, in actuality, claim 112 depends from claim 103 and claim 113 depends from claim 102.

***Claim Rejections - 35 USC § 112, second paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 110, 112 and 113 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 110, 112 and 113 recite the phrase "a sequence having at least about 45% similarity" (emphasis added). This phrase renders the claim indefinite because it is unclear if the

sequence can have less than 45% similarity because "at least" implies that the similarity must be 45% or greater, while "about" implies that the similarity can be greater than or less than 45%.

Claim 110 additionally recites the phrases, "substantially as set forth in SEQ ID NO: 2" and "derivative homologue". These phrases also render the claim indefinite because: 1) It is unclear how similar/identical a sequence must be to SEQ ID NO: 2 in order to be considered "substantially as asset forth in SEQ ID NO: 2" as the neither the claim nor the specification clearly defines "substantially"; and 2) It is unclear what a "derivative homologue" is as it is undefined in the claims and the specification.

Claims 112 and 113 are indefinite because they depend from claims 103 and 102, respectively. Claims 102 and 103 are directed to non-elected subject matter and are withdrawn from consideration.

***Claim Rejections - 35 USC § 112, first paragraph***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 109-113 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims encompass nucleic acid sequences which are different from those disclosed in the specification, and include variants and derivatives for which no written

description is provided in the specification. Only several species that fall within this large genus are disclosed in the specification by specific SEQ ID NOS. Thus, applicant has express possession of only the nucleic acid sequences of SEQ ID NOS: 1, 3, 5, 6 and 8-15, in a genus which comprises hundreds of millions of different possibilities considering every possible derivative of a nucleic acid encoding ELF5.

The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no structural limitations or requirements which provide guidance on the identification of sequences which meet the functional limitations are provided.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that:

> "In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (Affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that:

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only certain specific SEQ ID NOS. are described, the specification does not described every possible derivative and does not offer guidance on which derivatives would be functional derivatives and which ones would be non-functional derivatives.

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acid sequences other than those expressly disclosed which represent functional derivatives of ELF5. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

### *Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 109-113 are rejected under 35 U.S.C. 102(b) as being anticipated by Bochert et al. (Biochem. Biophys. Res. Comm. 246:176-181; May 8, 1998).

Claim 109 is drawn to an isolated nucleic acid encoding ELF5 wherein said ELF5 comprises an Ets domain. The specification discloses isolated nucleic acids that are derivatives of ELF5 and which are assigned sequence identifiers (SEQ ID NO.). However, the claim does not specifically limit the isolated nucleic acid to any particular sequence. In fact, the only limitation of the isolated nucleic acid of claim 1 is that the nucleic acid encodes a polypeptide comprising an Ets domain. Bochert teaches an isolated nucleic acid that encodes a polypeptide that meets this limitation (i.e., a nucleic acid which encodes a polypeptide comprising an Ets domain; see p. 178, Figure 1).

Claim 110 is drawn to an isolated nucleic acid or derivative of the amino acid sequence substantially as set forth in SEQ ID NO. 2 or a derivative thereof that has at least 45% similarity to at least 10 contiguous amino acids. Bochert teaches an isolated nucleic acid that encodes an amino acid sequence that is 100% identical to 11 contiguous amino acids of SEQ ID NO. 2 (see p. 178, Figure 1 and attached sequence alignment of amino acids 237-248).

Claim 111 is drawn to an isolated nucleic acid sequence that is a derivative of SEQ ID No. 1 and is capable of hybridizing to SEQ ID NO. 1 under low stringency conditions. Furthermore, the claim encompasses any derivative (such as a fragment) of SEQ ID NO. 1, regardless of size. Bochert teaches a nucleic acid sequence comprising derivatives which would bind to the nucleic acid of SEQ ID NO: 1 under low stringency conditions (e.g. the sequence ATG, is a nucleic acid fragment taught by Bochert which would hybridize to SEQ ID NO. 1 under low stringency conditions).

Claim 112 is drawn to the nucleic acid of claim 111 which further encodes a sequence that has at least about 45% similarity to at least 10 contiguous amino acids of SEQ ID NO. 2. Bochert also teaches the isolated nucleic acid encodes an amino acid sequence that is 100% identical to 11 contiguous amino acids of SEQ ID NO. 2 (see p. 178, Figure 1 and attached sequence alignment of amino acids 237-248).

Claim 113 is drawn to the nucleic acid of claim 110 substantially as set forth in SEQ ID NO. 1. It is noted that the term "substantially as" is not limiting. Therefore, Bochert teaches nucleic acid (as set forth in claim 110) which is "substantially as" set forth in SEQ ID No. 1.

Therefore, the invention as a whole is clearly anticipated by Bochert.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
August 22, 2002

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER